Remarks

Prior to this amendment, claims 1-12 and 19-35 were pending in this application. Claims 19, 20, 25-27 are amended. Claim 24 is canceled and claims 36-48 are added herein.

Support for the amendments of claims 19, 20, and 25-27 can be found in the specification at least at page 12, lines 19-28. Support for new claims 36-46 can be found in the specification at least at page 12, lines 19-28, page 22, lines 18-20, and the sequence listing. Support for new claims 47 and 48 can be found in the specification at least at page 12, lines 9-10.

No new matter has been added by these amendments. Unless specifically stated otherwise, none of these amendments are intended to limit the scope of any claim. Applicants reserve the right to prosecute any removed subject matter in a continuation application. After entry of this amendment, **claims 1-12, 19-23, 25-30, and 32-48 are pending in this application**. Reconsideration of the pending claims is respectfully requested.

Examiner Interview

Applicants thank Examiner Navarro for the courtesy of a telephone conference on July 15, 2008 with their representative, Dr. Anne Carlson. During the interview, the rejections under 35 U.S.C. §112, first paragraph were discussed. Although express agreement was not reached, it is believed that this response is in accordance with that discussion.

Allowance of Claims and Withdrawal of Claim Rejections

Applicants thank Examiner Navarro for withdrawing the rejections in the Office action dated June 12, 2007, and for stating that claims 1-12, 29, 30, and 32-35 are allowed.

Claim Rejections Under 35 U.S.C. §112, first paragraph (written description)

Claims 19-28 are rejected under 35 U.S.C. §112, first paragraph, as allegedly the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office action alleges that the "specification and claims do not indicate what distinguishing attributes are shared by the

members of the genus." Applicants respectfully traverse this rejection. Claim 24 is canceled, rendering the rejection of this claim moot. Solely to advance prosecution in this case, claims 19 and 26 are amended to be directed to "a human defensin." Claims 20-23, 25, and 27-28 depend, directly or indirectly, from claim 19 or claim 26, and incorporate all of the limitations thereof.

In light of the amendments of claims 19 and 26, Applicants submit that the claims are directed to the genus of human defensin polypeptides having distinguishing attributes. Moreover, the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed.

MPEP §2163 states the following:

> The written description requirement for a claimed genus may be satisfied through ***sufficient description of a representative number of species*** by actual reduction to practice . . ., reduction to drawings . . ., or by ***disclosure of relevant, identifying characteristics***, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics . . . Description of a representative number of species ***does not require the description to be of such specificity that it would provide the individual support for each species that the genus embraces***" (emphasis added).

Applicants submit that the specification provides *a sufficient description of a representative number of species* in the genus of human defensin proteins. For example, human defensins are described as alpha-, beta-, and theta-defensins, of which representative examples of human alpha-defensins include HNP-1, HNP-2, HNP-3, HNP-4, HD-5, HD-6, and Def-X, and representative examples of human beta-defensins include hBD-1, hBD-2, hBD-3, hBD-4 (see, for example, the specification at page 8, lines 29-32; page 12, line 9 through page 13, line 5). In addition, the specification clearly describes defensin variants having 95%, and 98% sequence identity (see, for example, page 22, lines 18-20). Thus, the specification clearly includes *a sufficient description of a representative number of species* for the genus of human defensins (including variants).

Applicants further submit that the specification discloses a number of *relevant, identifying characteristics* of human defensin proteins (*i.e.* structural characteristics) that would enable one of skill in the art to readily identify members of this genus, even if they were not specifically described in the specification. For example, the specification discloses that defensins (i) are small, cationic peptides that have six conserved cysteine residues that form three disulfide bonds (specification at page 12, lines 9-10); and (ii) are arginine-rich (specification at page 8, lines 29-30).

MPEP §2163 states that it is not required to *provide individual support for each species that the genus embraces* in order to sufficiently describe the genus. Thus, Applicants submit that there is no requirement that all encompassed species be specifically identified in the specification. As discussed above, the specification provides a number of relevant, identifying characteristics that sufficiently describe the genus of human defensin proteins. Any proteins not specifically described in the specification that fall within the genus of human defensins also display the structural and functional characteristics used to describe the existing members of the genus. Accordingly, although the specification may not disclose every member of the claimed genus, if the undisclosed species (including those species that have not yet been identified) possess the characteristics that define the members of the genus, then the undisclosed species are sufficiently described.

As stated in *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960):

> [I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species ***if a genus is sufficiently identified in an application by "other appropriate language"*** (emphasis added).

As discussed above, the specification discloses multiple members of the genus of human defensin proteins known at the time the application was filed. Although additional members of the genus of defensins are not specifically identified by name, the specification clearly uses "other appropriate language," such as disclosing that defensins (i) are small, cationic peptides that have six conserved cysteine residues that form three disulfide bonds; and (ii) are arginine-

rich (specification at page 8, lines 29-30; page 12, lines 9-10). Thus, based on the specification, one of skill in the art would clearly be able to identify which other proteins should be included in the genus of human defensin proteins. Thus, the specification clearly provides sufficient support for the structural attributes that describe the members of the genus of defensins.

Applicants further submit that characteristics of defensin proteins were well known to those of skill in the art at the time the application was filed (see, for example, Lehrer and Ganz, *Curr. Opin. Immunol*, 14:96-102, 2002 – **Exhibit A**; Risso, *J. Leuk. Bio*., 68:785-792, 2000 - **Exhibit B**; Bals, *Respir. Res.* 1:141-150, 2000 - **Exhibit C;** Bauer *et al., Prot. Sci.*, 10:2470-2479, 2001 – **Exhibit D** ; Tran *et al., J. Biol. Chem*, 277 :3079-3084, 2002 – **Exhibit E**; Raj *et al., Biochem. J.*, 347:633-641, 2000 – **Exhibit F**) and that these characteristics were relied upon to identify members of the genus. Applicants particularly note that these Exhibits clearly indicate that at the time the application was filed, the presence and location of the conserved cysteines not only identified proteins as functional defensins, but categorized them as alpha-, beta- or theta-defensins. Furthermore, despite sequence variation among the members of the alpha-defensin, beta-defensin, and theta-defensin families, the six cysteine residues are consistently conserved, even across species. Thus, those of skill in the art at the time the application was filed relied on the identification of the six cysteine residues in order to classify proteins as defensins. After the filing of the application, new members of the genus of defensin proteins were likewise identified (Paziger *et al., Curr. Pharm. Des*., 13:3096-3118, 2007 – **Exhibit G**; Sugiarto and Yu, *Biochem. Biophys. Res. Comm*., 323:721-727, 2004 - **Exhibit H**). Thus, those of skill in the art could readily identify members of the genus of human defensins, both before and after the filing of the subject application. In addition, those of skill in the art could identify variants of defensins having the six conserved cysteines.

The specification also clearly describes how to make conservative substitutions (specification at page 21, line 22 through page 22, line 20) and, as discussed above, it was well known to those of skill in the art at the time the application was filed which conserved residues cannot be substituted. Thus, Applicants submit that one of skill in the art could easily envision variants of the claimed human defensins (including variants having 95% or 98% sequence

identity), based on the teaching of the specification, what was known in the art at the time the application was filed.

Applicants submit that the subject matter encompassed by claims 19-23 and 25-28 is sufficiently described by the specification. In view of the above discussion, reconsideration and withdrawal of the written description rejection of claims 19-23 and 25-28 is respectfully requested.

Request for Interview

Applicants believe the application is in condition for allowance and such action is requested. If an additional rejection is asserted, or if the present rejection is maintained, Examiner Navarro is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution, and may be useful prior to Appeal. This request is being submitted under MPEP §713.01, which indicates that an interview can be arranged in advance by a written request.

Respectfully submitted,

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